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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/695,025	10/28/2003	Guang Wei Lu	01088/2/US	5691

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EXAMINER	
CLAYTOR, DEIRDRE RENEE	
ART UNIT	PAPER NUMBER
1617	

DATE MAILED: 09/25/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/695,025	LU ET AL.	
	Examiner	Art Unit	
	Renee Claytor	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *28 October 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-22* is/are pending in the application.

4a) Of the above claim(s) *13-15 and 18-20* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-12,16,17,21 and 22* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *5/21/2004*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Applicant's election of Group I is hereby acknowledged. Applicant's election of the species glyceryl monolaurate as the skin permeation enhancer is further acknowledged. The election was made without traverse. Claims 1-12, 16-17, and 21-22 are being examined on the merits herein and claims 13-15 and 18-20 are withdrawn from consideration as they don't read on the elected species. The election requirement is deemed proper and made FINAL.

Priority

This application claims priority to U.S. Provisional Application 60/428,208 filed on 11/21/2002. Applicant's priority is acknowledged.

Objections

The disclosure is objected to because of the following informalities:

Paragraphs 0125 and 0127, Example 2 on page 28 states that the time course of skin permeation is shown graphically in Figure 3; however, no Figure 3 is given with the drawings and is not listed in the Brief Description of Drawings in the specification.

Paragraph 0130, Example 4 on page 30 states that the compositions are 1-1, 1-2, and 1-3; however, Table 4 lists the compositions as 3-1, 3-2, and 3-3.

Paragraph 0137, Example 6 states that composition 5-7 through 5-24 were tested for skin permeation; however, the results in Table 6 only show compositions 5-7 through 5-22.

Appropriate correction is required.

Claim Rejections – 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 1 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. It is unclear what the recitation of "....zero to less than an active agent solubilizing effective amount...." is conveying. Is it referring to less than zero of a solubilizable active agent?

Claim Rejections – 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-12, 16-17, and 21-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Venkateshwaran et al. (WO 98/18416) in view of Lu et al. (WO 02/096435).

Venkateshwaran et al. teach a transdermal drug delivery system comprising a matrix system with an occlusive backing, an adhesive and a reservoir system for

holding the composition against the skin surface for administration (meeting the limitations of claims 1, 7-11; Pg. 11, lines 1-10 and 33-35; Pg. 12, lines 1-4; Claims 1, 4-6, 13). The transdermal drug delivery system may be comprised of a matrix form with a backing and a release liner on the surface of the adhesive opposite the film backing (encompassing claim 22; Pg. 11, lines 1-15). It is also taught that the preferable weight range of the adhesive of the transdermal drug delivery system is 70 to 99.5% by weight (encompassing claim 21; Pg. 16, lines 23-25). Venkateshwaran also teach that a broad category of pharmaceutically-active agents which are lipophilic or hydrophilic can be used in the transdermal delivery system (Pg. 6, lines 18-23, examples).

Venkateshwaran does not teach a pharmaceutical composition comprising valdecoxib or parecoxib as the active drug and glyceryl monolaurate as the permeation enhancer.

Lu et al. teach a dermally deliverable pharmaceutical composition that is suitable for direct application to the skin and permits absorption into the skin (Pg. 9, lines 2-5) with the therapeutic agent being a COX-2 inhibitor, preferably valdecoxib and/or a prodrug thereof, for example parecoxib sodium (Page 11, lines 24-26 and claim 7). It is also taught that the composition contains a permeation enhancer, and that the preferred permeation enhancer is glyceryl monolaurate (Pg. 18, lines 11-12). Lu et al. teach that the composition can comprise 1.25-10% of the COX-2 inhibitory drug and 2-20% of the skin permeation enhancer (encompassing claim 21; Pg. 20, lines 19-24).

Accordingly, it would have been obvious to one having ordinary skill in the art at the time the invention was made to combine the teachings of Venkateshwaran et al.,

which teaches a transdermal drug delivery system (e.g. a patch) comprising a matrix system with an occlusive backing, an adhesive and a reservoir system for holding a drug against the skin for dermal administration, with Lu et al. which teaches a dermally deliverable pharmaceutical composition, comprised of valdecoxib and parecoxib and glyceryl monolaurate, for direct application onto the skin. One having ordinary skill in the art at the time the invention was made would have been motivated to utilize a transdermal delivery system, such as a patch of Venkateshwaran et al., for delivery of parecoxib to a patient suffering from a COX-2 mediated disorder because of the convenience, noninterrupted therapy, improved patient compliance and reduction of side effects that is often observed with alternate forms of drug administration (e.g., oral, intravenous) as is taught by Venkateshwaran et al. (Pg. 1, lines 21-29).

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-12, 16-17, and 21-22 are provisionally rejected on the ground of nonstatutory double patenting over claims 1-3, 7-12, 16-17, and 21-22 of copending Application No. 10/683,943. This is a provisional double patenting rejection since the conflicting claims have not yet been patented.

The subject matter claimed in the instant application is fully disclosed in the referenced copending application and would be covered by any patent granted on that copending application since the referenced copending application and the instant application are claiming common subject matter, as follows: the instant claims are drawn to a composition comprising a backing sheet that is flexibly conformable to the area of skin and a coating on the proximal surface of the backing sheet that comprises an adhesive and an active agent comprising valdecoxib or a prodrug thereof or a salt thereof. The claims of application No. 10/683,943 are likewise drawn to a composition comprising a backing sheet that is flexibly conformable to the area of skin and a coating on the proximal surface of the backing sheet that comprises an adhesive and a water-soluble active agent selected from the group consisting of selective COX-2 inhibitory drugs, prodrugs and salts thereof. It is known within the art that parecoxib is a prodrug of valdecoxib and both are COX-2 inhibitors; therefore, it would be obvious to one having ordinary skill in the art to utilize either of those drugs in the pharmaceutical composition as claimed.

Furthermore, there is no apparent reason why applicant would be prevented from presenting claims corresponding to those of the instant application in the other copending application. See *In re Schneller*, 397 F.2d 350, 158 USPQ 210 (CCPA 1968). See also MPEP § 804.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Renee Claytor whose telephone number is 571-272-8394. The examiner can normally be reached on M-F 8:00-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Renee Claytor

JOHANN RICHTER
SUPERVISORY PATENT EXAMINER
GROUP 1616